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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,786	02/08/2002	Eugene O. Major	GRT/2370-67	9275

23117 7590 03/05/2007  
NIXON & VANDERHYE, PC  
901 NORTH GLEBE ROAD, 11TH FLOOR  
ARLINGTON, VA 22203

EXAMINER
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HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
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1649

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/05/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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# Office Action Summary

Application No.

09/936,786

Applicant(s)

MAJOR ET AL.

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4, 12, 13, 33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 12, 13, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Response to Amendment***

1. The amendment filed 12/8/06 has been entered.
2. Applicant's arguments filed 12/8/06 have been fully considered but they are not deemed to be persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1-4, 12-13 & 33-34 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14 & 16 of U.S. Patent No. 5,753,491, for the reasons made of record in Paper NOs: 1/31/05, 20051012 & 20060830, and as follows.

In contrast to Applicants' assertions on page 3 of the response, claims 14 & 15 of '491 appear to still be the same as the immortal human multipotent CNS neural stem cells of the instant invention, for one of two reasons:

1) '491 cells are recited as being "an immortalized human fetal neuro-glial cell line", which further expresses "vimentin, MHC Class I and T protein", which are merely inherent properties of these cells, and which do not change the structure of the claimed cells. By definition, a "neuro-glial cell line" possesses the ""potential to differentiate toward neuronal

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cells or glial cells”, otherwise it would not be a “neuro-glial cell line”. See also column 6, lines 56-63, wherein “astrocytes” and “oligodendrocytes” are the “glial” cells of the Central Nervous System, and column 7 (lines 58-65) & Table 2 where “SVG cells” are described. Page 3 of the instant application then directs the skilled artisan to “See U.S. Patent Nos. **5,753,491**; 5,869,463 and 5,690,927” [emphasis added] for description of the same “SVG cells” used in the instant invention. As previously made of record, the sole reason this is not a statutory double patent rejection is because the claim languages is not identical. Nevertheless, the issue remains that Applicants are not permitted to extend the patent term of that claimed in ‘491 through this application. Therefore, because the instant cells are currently indistinguishable from the cells claimed in the instant application, even though these cells must be ChTx-, the cells of ‘491 reasonably are also inherently ChTx-, as now discovered, or as now claimed here; absent evidence to the contrary, which Applicants have failed to provide.

2) Applicants argue on page 4 of the response that “[m]ultipotent stem cells can be either cholera-toxin negative or cholera-toxin positive”. Therefore, the “immortalized human fetal neuro-glial cell line” claimed in ‘491 also would be either “cholera-toxin negative or cholera-toxin positive”, or both. Thus, the cells of ‘491 are generic to the instant invention, and therefore, encompass the cells of the instant invention.

5. Claims 1-4, 12-13 & 33-34 stand rejected under 35 U.S.C. 102(e) as being anticipated by Major et al (U.S. Patent 5,753,491; IDS Ref #2), for the reason made of record in Paper NOs: 1/31/05, 20051012 & 20060830, and as follows.

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In contrast to Applicants' assertions on pages 3-4 of the response, the claims still appear to be the same as Major's immortal human multipotent CNS neural stem cell line, because similar methods were used to generate both Major's and the multipotent immortal CNS stem cell line of the instant invention; thereby, reasonably also making the cells of Major et al. ChTx negative neural stem cells. As previously made of record, simply put, similar methods deriving multipotent cells from SVG cells reasonably and inherently result in structurally identical products, in which no evidence has been provided by Applicants to show that Major's cells are different and distinguishable from that now claimed. In other words, multipotent neural stem cells are multipotent neural stem cells, no matter what antigens are later discovered to be expressed by these otherwise identical cell lines.

Accordingly, and in contrast to Applicants' arguments on page 4 of the response, it has been established by the courts that a product (i.e., as it relates to the claimed CNS multipotent cell line) inherently possesses characteristics of that product (i.e., any expressed antigens, or non-expressed antigens, such as being cholera-toxin negative), and that:

"the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Accordingly, since the issue in the present appeal is whether the prior art factor is identified or patently indistinct from that of the material on appeal, appellants have the burden of showing that inherency is not involved". *Ex parte Gray*, 10 USPQ 2d 1922 (1989); *In re Best*, 195 USPQ 430 (CCPA 1976).

Lastly, it is noted that the courts have held that when the prior art product reasonably appears to be the same as that claimed, but differs by process in which it is produced, a rejection of this nature is eminently fair and the burden is upon the appellants to prove, by comparative evidence, a patentable difference (*In re Brown*, 173 USPQ 685 (1972)).

In summary, Major et al disclose isolated, immortalized CNS human fetal neuro-derived cell lines, which “generally produce progenitor neuronal and glial cells” (e.g., column 7, lines 22-37); thereby, being multipotent, by definition (i.e., as it relates to claims 1-3, 12 & 33). Cells derived from SVG cells are also described by Major (e. g., column 4, lines 66 - column 5, line 1; column 7, lines 57-65), which further appear identical to those cells (i.e., multipotent cells) described on pgs 3 & 15-17 of the instant specification (i.e., as it also relates to claims 1-3, 12 and 33). In that all of these cells described by Major et al reasonably appear identical to the alternative names of “NG1, NG2 and NG3” cells recited in claim 13, and inherently express markers that uniquely define what constitutes a multipotent stem cell, the limitations of claims 4 and 13 are met; absent evidence to the contrary. Finally, in that the process of producing multipotent neural stem cells does not materially change the multipotent neural stem cell product produced, the limitations of claim 34 are anticipated.

6. Claims 1-4, 12-13 & 33-34 stand rejected under 35 U.S.C. 102(e) as being anticipated by Weiss et al (U.S. Patent 5,750,376; IDS Ref #3), for the reason made of record in Paper NO: 1/31/05, 20051012 & 20060830, and as follows.

In contrast to Applicants’ assertions on page 4 of the response, the claims still reasonably appear to be identical with Weiss’ human multipotent CNS neural stem cell lines, which are further described as “neurospheres” (i.e., as it especially relates to claim 34). No features that structurally distinguish the instant claims from that taught by Weiss have been made of record, or are apparent, because both the cells of the instant invention and Weiss’ multipotent neural stem cells/neurospheres “have the potential to differentiate toward neuronal cells or glial cells” (i.e., as

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recite in claims 1), and because both cells form “neurospheres” (i.e., as recited in claim 34), and therefore, reasonably should be also cholera-toxin negative (ChTx-), by definition; absent evidence to the contrary. Applicants have failed to provide any evidence, for example, in a side-by-side comparison that distinguishes Weiss’ cells from the instant invention (e.g., as being ChTx+ versus ChTx-), which results in correspondingly different functional characteristics that distinguishes these multipotent CNS cell lines. Simply put, neurospheres are neurospheres are neurospheres, which inherently express, and not express, those antigens that characterize multipotent neural stem cells as being multipotent neural stem cells, as taught by Weiss et al.

In summary, Weiss et al disclose isolated human CNS multipotent neural stem cell lines (i.e., neurospheres; as it relates to claims 33-34), which are clonally-derived/ “immortalized” and have the “potential to differentiate toward a neuronal cell or a glial cell” (e.g., column 11, lines 49-56) columns 13, 17- 18, 21-22, 36 and 48; as it relates to claims 1-3 and 12). In that the multipotent stem cells described by Weiss et al reasonably appear identical to the alternative names of “NG1, NG2 and NG3” cells recited in claim 13, and inherently express markers that uniquely define what constitutes a multipotent neural stem cell (e. g., column 56), the limitations of claims 4 and 13 are met; absent evidence to the contrary. Finally, in that the process of producing multipotent neural stem cells does not materially change the multipotent neural stem cell product produced, the limitations of claim 34 are anticipated.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.  
February 28, 2007

ROBERT C. HAYES, PH.D.  
PRIMARY EXAMINER